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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,782	10/31/2001	Ronald B. Luther	RLUTHER.013A	8602

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/18/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/003,782

Applicant(s)

RONALD LUTHER

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9,11,12,14-18 and 20 is/are rejected.
- 7) ☒ Claim(s) 3,10,13 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-9, 11, 12, 14-18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bogert, 5,599,310.

Bogert discloses a needle (16), an over-the-needle catheter (12), including a hub (14), disposed about the needle; a hub trap (28) comprising first and second arms (distal portion of 48); an elongate sheath (30 and proximal portion of 48); and a slider (20) connected to a proximal end of the needle, the slider being movable along the sheath from a distal to a proximal position; wherein when the slider is in the distal position, the needle extends through a locking structure of the hub trap and retains the first and second arms in a closed position wherein the hub is trapped between the first and second arms, (see Figure 22) ; and when the slider is in the proximal position, a

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distal tip of the needle is proximal of the locking structure and the first and second arms are in an open position wherein the hub is released from the hub trap, (see Figure 23).

As to claim 2, the hub (14) is released only when the slider is in the proximal position (see Figure 23), and remains trapped within the hub trap when the slider is in the distal position (see Figure 23.)

As to claim 6, the arms are pivotable about an axis substantially perpendicular to a longitudinal axis of the protector (see Figures 2A and 3.)

As to claim 9, the sheath (30) comprises a first cylindrical member.

As to claim 11, the hub (14) further comprises a flat fin (see proximal end of 14) defining a plane perpendicular to a longitudinal axis of the protector.

As to claim 12, Bogert discloses a needle; a catheter, including a hub disposed about the needle; an elongate sheath (30 and proximal portion of 48); a hub trap (28) comprising first and second arms (distal portion of 48) (see column 3, lines 64-65 and Figures 2A and 2B and 23) connected to a first end of the sheath, the first and second arms being selectively engageable with the hub; and a slider (20) connected to a proximal end of the needle, the slider being disposed about the sheath and moveable therealong from a distal position to a proximal position; wherein when the slider is in the distal position, the needle extends through a locking structure of the hub trap and retains the first and second arms in a closed position wherein the hub is trapped between the first and second arms, (see Figure 22) ; and when the slider is in the proximal position, a distal tip of the needle is proximal of the locking structure, the first

and second arms are in an open position wherein the hub is released from the hub trap, (see Figure 23), and the needle is disposed entirely within the sheath (see Figure 23.)

As to claims 4 and 14, when the arms are in the open position, interlocking fingers of the first and second arms block the needle and prevent it from reemerging from the sheath (see Figure 23.)

As to claims 5 and 15, a stop (105) at a proximal end of the sheath prevents the slider from disengaging the sheath via the proximal end.

As to claim 6, the arms are pivotable about an axis substantially perpendicular to a longitudinal axis of the protector (see Figures 2A and 3 and 23.)

As to claims 7 and 16, the slider (20) further comprises a hollow interior chamber in fluid communication with a central lumen of the needle (see Figure 23.)

As to claims 8 and 17, at least a portion of the slider is transparent and allows viewing of the interior chamber (see column 6, lines 11-14.)

As to claims 9 and 18, at least a portion of the sheath (proximal portion of 48) is substantially cylindrical.

As to claim 20, the hub (14) further comprises a substantially flat fin (see flange at proximal end of 14) defining a plane substantially perpendicular to a longitudinal axis of the protector.

Claims 1, 2, 9 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Funderburk et al., 6,520,938. Funderburk et al. discloses a needle (18), an over-the-needle catheter (12), including a hub (14), disposed about the needle; a hub trap (56)

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comprising first and second arms; an elongate sheath (34); and a slider (16) connected to a proximal end of the needle, the slider being movable along the sheath from a distal to a proximal position; wherein when the slider is in the distal position, the needle extends through a locking structure of the hub trap and retains the first and second arms in a closed position wherein the hub is trapped between the first and second arms, see Figure 6; and when the slider is in the proximal position, a distal tip of the needle is proximal of the locking structure and the first and second arms are in an open position wherein the hub is released from the hub trap, see Figure 2.

As to claim 2, the hub (14) is released only when the slider is in the proximal position, and remains trapped within the hub trap when the slider is in the distal position.

As to claim 9, the sheath (34) comprises a first cylindrical member.

As to claim 11, the hub (14) further comprises a flat fin (see proximal end of 14 in Figure 2) defining a plane perpendicular to a longitudinal axis of the protector.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Funderburk et al., 6,520,938. Funderburk et al. discloses the invention substantially as claimed, see above, except for the slider being transparent.

However, Funderburk teaches that the device can be manufactured from medical grade plastic or the like, see column 2, lines 10-14. It would have been obvious to form the Funderburk et al. device from medical grade plastic or the like, which are known in the art to be transparent.

Allowable Subject Matter

Claims 3, 10, 13 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the combination of elements wherein when the needle contacts the arms, it provides a force counteracting a spring force biasing the arms toward the open position, was not found in the prior art search. Also not found in the prior art search is a sheath comprising a first and second telescoping members, in addition to a hub trap with first and second arms, wherein the needle extends through a locking structure of the hub trap and retains the first and second arms in a closed position wherein the hub is trapped between the first and second arms.

Response to Arguments

Applicant's arguments filed August 22, 2003 have been fully considered but they are not persuasive. On page 6, Applicant states that Examiner has identified the needle guide (34) of Funderburk as a sheath, and the inserter hub (16) as a slider, and Applicant asserts that these components could not be considered a sheath and slider, as described in Applicant's application. In response, Examiner asserts that nothing in Applicant's claims precludes this interpretation made by Examiner in the above rejection.

On page 7, Applicant argues that hub (16) of Funderburk is not movable along the needle guide (34). In response, Examiner reasserts that member (16) is moveable along member (34), (see operation of the device from Figure 2 to Figure 6, after sliding member 16 along member 34.)

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Koenig, Jr. et al., 5,135,502, discloses a telescoping sheath, and Luther et al., 6,595,954, discloses a catheter and insertion needle assembly.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.


LONG V. LE
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11/16/03